

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Patent Application No. 10/802,280

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Applicant: Urata et al.

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P.O. Box 1450
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DECLARATION UNDER 37 C.F.R. § 1.131 OF
YASUO URATA AND TOMOHIRO ISHIKAWA

We, Yasuo Urata and Tomohiro Ishikawa, do hereby declare:

1. We are the inventors of the subject matter disclosed and claimed in the above-identified patent application ("the present invention").
2. The present invention was conceived of and reduced to practice prior to June 21, 2001.
3. As merely an example of both the conception and reduction to practice of the present invention, Exhibit A is attached to this Declaration.
4. Exhibit A is a true and accurate copy of a document prepared before June 21, 2001. Dates and information irrelevant to the purposes of this Declaration have been redacted from Exhibit A as attached hereto. Exhibit A shows the results of administering to patients once per day a therapeutically effective amount of S-[2-((1-(2-ethylbutyl)cyclohexyl)carbonyl)amino]phenyl] 2-methylpropanethioate (JTT-705) in a

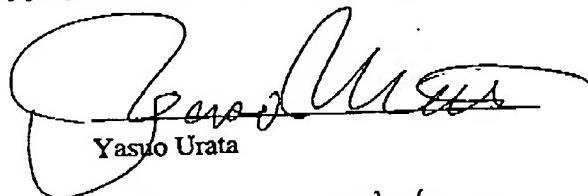
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Declaration Under 37 C.F.R. § 1.131

pharmaceutical composition with food, in which the food is not part of the pharmaceutical composition.

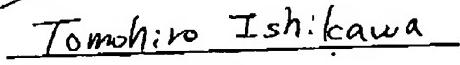
5. We hereby declare that all statements made herein of our own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 11/7/06



Yasuo Urata

Date: 11/15/06



Tomohiro Ishikawa

Tomohiro Ishikawa

EXHIBIT A

Name of Sponsor\Company: Japan Tobacco Inc.			
Name of active ingredient: JTT-705			
<u>Food interaction study</u>			
The plasma pharmacokinetic parameters JTT-705 in the fed and the fasted states are presented in the following table:			
Parameter	Dose of JTT-705 900 mg (fasted)	Dose of JTT-705 900 mg (fed)	Ratio (fed:fasted)
AUC(0-t)* (μ g.h/mL)	6.21 (46.9)	10.2 (19.0)	1.65
AUC(0- ∞)* (μ g.h/mL)	7.97 (46.7)	12.5 (17.4)	1.57
C _{max} * (μ g/mL)	0.423 (37.1)	0.955 (26.1)	2.26
t _{max} [†] (h)	5.00 (2.00-6.00)	4.00 (2.00-6.00)	NA
t _{1/2} [‡] (h)	16.5 (14.1-22.4)	15.4 (12.6-18.6)	0.935

* Geometric mean (geometric CV%)

† Median (min-max)

‡ Harmonic mean (min-max)

NA = Not applicable